

Cashew Nut Shell Liquid - Comments of Environmental Defense

(Submitted via Internet 10/25/02)

Environmental Defense appreciates this opportunity to submit comments on the robust summary/test plan for cashew nut shell liquid.

The test plan and robust summaries for Cashew nut shell liquid (CNSL) were prepared by Cardolite Corporation. They were clearly written and documented and the sponsor's rationale for new testing was easy to follow and generally persuasive. We do, however, disagree with the proposal to conduct acute toxicity tests. In addition, we have some suggested revisions that could improve the test plan.

CNSL is obtained as a byproduct during the process of removing cashew kernels from the nut. This is accomplished using hot oil or roasting allowing for the collection of technical grade CNSL. This can be distilled to remove polymeric substances and to achieve consistency across preparations. The sponsor states that CNSL has a wide array of uses and applications including friction-resistant components in brake linings, adhesives, plasticizers, rubber additives and paint and varnish additives. Distilled CNSL is comprised of 78% cardanol, 8% cardol and 2% polymeric substances. The identity of the other 12% is not indicated in the test plan. We recommend that a more complete listing of the constituents of CNSL be included in the test plan to permit a more complete toxicological assessment of CNSL.

The sponsor proposes to use distilled CNSL as the test substance for additional health effects testing. We agree with this selection as it reasonably represents all of the applications of CNSL. Specific comments on proposed studies are provided below. We did not review the environmental and ecological sections of the test plan.

1. Worker exposure studies have shown that CNSL is a skin irritant and sensitizer in a high proportion of those exposed in the workplace so the use of protective measures to prevent exposures have been put into place. The sensitizing actions of CNSL clearly indicate that CNSL is biologically active, so it is particularly clear that additional studies to fill existing knowledge gaps are needed.

2. No data is available for reproductive, developmental or repeat dose toxicity. Therefore, we agree with the sponsor's proposal to conduct a combined study (OECD 422) to evaluate these 3 endpoints. We strongly support using a combined protocol.

3. The sponsor also proposes to conduct an acute toxicity study on CNSL. We do not agree that this study is necessary because the range finding study to select doses for the OECD 422 study will provide adequate high-dose toxicity data for screening-level purposes.

4. We agree that there is adequate genetic toxicity data to conclude that CNSL is not genotoxic.

5. Although not required as part of the HPV program, a yeast screen assay was conducted to assess CNSL for estrogenic activity. While this assay showed no evidence that CNSL possesses estrogenic activity, it is important to note that the yeast screen would not detect estrogen activity arising as a consequence of metabolism of a substance by mammalian enzymes. Therefore, it is not possible to conclude, at this time, that CNSL is not estrogenic in vivo.

Thank you for this opportunity to comment.

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